K072315

4. 510(k) Summary

SEP 18 2007

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number:	1625507
Address of Manufacturer:	Medtronic Powered Surgical Solutions 4620 North Beach Street Fort Worth, TX 76137 (805) 968-1546 ext. 1770 Fax: (805) 968-9336
Contact Person:	Jeffrey Henderson
Date:	August 16, 2007
Trade or Proprietary Name:	Midas Rex® Curved Bur
Common usual or Classification Name:	Dissecting tool – Powered Simple cranial bur (882.4310)
Predicate Device Identification:	Medtronic Midas Rex® Legend® Pneumatic High Speed System (K020069)

Description: Midas Rex Curved Bur is a sterile, single use, one piece device which includes the dissection tool (bur head, bur wire, bur tang) and the protective tube / cooling sleeve / hub. The hub connects and locks into the existing Legend telescoping attachment base. Legend telescoping attachment base connects to the Legend motor. The motor provides the power to rotate the dissecting tool / bur. The attachment / tube provide support and stability to the dissecting tool. The bur head which may be fluted or diamond coated, is the actual cutting tip on the device.

Intended Use: Midas Rex Curved Burs are designed to work with all Legend motors through the Legend Telescoping attachment base under the recommended operating range for these motors. Legend motor provides the power to operate the telescoping attachments base, which then transmits the motion to activate the Curved Bur wire intended to cut and/or remove bone and biomaterials in the surgical procedures. Midas Rex Curved Burs are single use, disposable tools that may be used only for one surgical procedure.

Intended Use of predicate device(s): The Legend Telescoping system is intended to be used with Legend Motors. Legend motor provides the power to operate the telescoping attachments base, which then transmits the motion to activate the Legend tools intended to cut and/or remove bone and biomaterials in the surgical procedures. Legend tools are single use, disposable tools that may be used only for

one surgical procedure. Legend telescoping tubes are disposable following multiple uses. Legend Telescoping system is part of Medtronic Midas Rex Legend Pneumatic High Speed system.

Technological comparison: Medtronic Powered Surgical Solutions submits that the device modification does not affect intended use, indication for use, device safety and effectiveness and fundamental scientific technology of the Curved Burs is the same as the previously reviewed and cleared Legend Telescoping System.

Based upon the summary above, Medtronic Powered Surgical Solutions determines substantial equivalence, safety, and efficacy of the Curved Bur products compared to the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 18 2007

Medtronic Powered Surgical Solutions
% Mr. Jeffrey Henderson
VP, Quality & Regulatory
Affairs
4620 North Beach Street
Fort Worth, Texas 76137

Re: K072315
Trade/Device Name: Midas Rex® Curved Burs
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: HBE, EQJ
Dated: August 16, 2007
Received: August 20, 2007

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

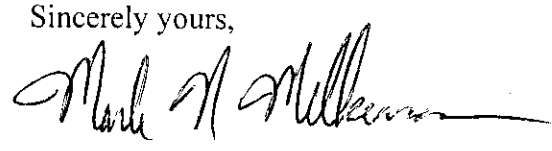
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Statement of Indications for Use

510(k) Number (if known): K072315

Device Name: Midas Rex® Curved Burs

Indications for Use:

The Midas Rex Curved Burs are intended for use in surgical procedures for the following medical applications: Neurosurgical; Spine; Ear, Nose and Throat (ENT), Orthopedic Surgery, and General and Plastic Surgery including Maxillofacial, Craniofacial and Sternotomy. The Curved bur will be used to cut and/or remove bone and biomaterial.

Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072315